RE-REGISTRATION DOSSIER		
Name of the Product	Oxymetazoline Hydrochloride Nasal Solution USP	**Module-1 – Administrative Information**
Brand Name	SINAREST NASAL DROPS	

1.6 Product information

1.6.1 Prescribing information (Summary of Product Characteristics)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS)

1.1 Strength:

Each ml contains:

Oxymetazoline Hydrochloride USP….. 0.5mg

In a buffered aqueous solution

1.2 Pharmaceutical form:

Nasal Solution

RE-REGISTRATION DOSSIER		
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2 QUALITATIVE AND QUANTITATIVE COMPOSITION:

2.1 Qualitative Declaration

Sr. No.	Name of Raw Materials	Specification
1	Oxymetazoline Hydrochloride	USP
2	Disodium Edetate	BP
3	Benzalkonium Chloride Solution (50% w/v)	BP
4	Sodium Dihydrogen Phosphate Dihydrate	BP
5	Disodium Hydrogen Phosphate Anhydrous (Dibasic Sodium Phosphate Anhydrous	BP
6	Water for Injection	BP

2.2 Quantitative Declaration

Standard Batch Size: 400 Lts

Sr. No.	Name of Raw Materials	Overages	Qty./ml in mg	Standard batch quantity
1	Oxymetazoline Hydrochloride	-	0.5	200.000 Gms
2	Disodium Edetate	-	0.5	0.200 kg
3	Benzalkonium Chloride Solution (50% w/v)	-	0.3	120.000 Gms
4	Sodium Dihydrogen Phosphate Dihydrate	-	20	8.000 kg
5	Disodium Hydrogen Phosphate Anhydrous (Dibasic Sodium Phosphate Anhydrous	-	2.25	0.900 kg
6	Water for Injection	-	1 ml (q. s.)	400.000 Lts

3 PHARMACEUTICAL FORM:

Nasal Solution

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) are indicated for Relief from nasal congestion due to cold, upper respiratory allergies or sinusitis.

4.2 Posology

The usual recommended dose of Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) in adults is 2 – 3 drops into each nostril bid. The usual recommended dose of Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) in children above 12 years of age is 1 drop into each nostril bid.

4.3 Method of administration: as directed by the physician.

4.4 Contraindications:

The use of Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) is contraindicated in patients with known hypersensitivity to its ingredients.

4.5 Special warnings and precautions for use:

Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) should be administered with caution in patients with hypertension, coronary artery disease, hyperthyroidism or diabetes mellitus. As with formulation, the use of the same pack of Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) by more than one person may spread infection.

4.6 Pediatric population

None.

4.7 Interaction with other medicinal products and other forms of interaction:

Clinically significant drug interactions may occur on concomitant administration of Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) with monoamine oxidase inhibitors, tricyclic antidepressants, β-adrenergic agents, methyldopa, reserpine & veratrum alkaloids.

4.8 Additional information on special populations

4.9 Pediatric population

None.

4.10 Fertility, Pregnancy and lactation:

4.10.1 General principles

4.10.2 Woman of childbearing potential / Contraception in males and females.

4.10.3 Pregnancy

4.10.4 Breastfeeding

4.10.5 Fertility

The safety during pregnancy has not been established. Since it is not known whether components of Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) are excreted in human milk, caution should be exercised when administering to nursing woman.

4.11 Effects on ability to drive and use machines:

No adverse effects known.

4.12 Undesirable effects:

Oxymetazoline Hydrochloride Nasal Solution USP (SINAREST NASAL DROPS) may occasionally cause local stinging or burning sensation, sneezing & dryness of the mouth & throat. Prolonged use may cause rebound congestion & drug induced rhinitis.

4.13 Overdose:

Overdosage may give rise to local irritation and rebound congestion. Treatment need only be symptomatic.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Oxymetazoline is a long acting and topical nasal decongestant. It acts by stimulating the α-adrenergic receptors of the vascular smooth muscle. This leads to constriction of the dilated arteriolar network within the nasal mucosa and thus reduces blood flow in the engorged edematous nasal area. The constriction results in shrinkage of the engorged mucous membrane, which promotes drainage, improves nasal ventilation and relieves the feeling of stuffiness.

5.2 Pharmacokinetic properties:

Oxymetazoline enters tissues rapidly and local vasoconstriction is normally achieved within 5-10 minutes of intranasal administration. The full effect lasts for 5-6 hours and then gradually subsides over the next 6 hours. Plasma half-life is 5-8 days with 30% of any absorbed drug being excreted in the urine unchanged and 10% being excreted in the faeces.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6.PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients:

Sr. No.	Name of Raw Materials	Specification
1	Disodium Edetate	BP
2	Benzalkonium Chloride Solution (50% w/v)	BP
3	Sodium Dihydrogen Phosphate Dihydrate	BP
4	Disodium Hydrogen Phosphate Anhydrous (Dibasic Sodium Phosphate Anhydrous	BP
5	Water for Injection	BP

6.2 Incompatibilities: None stated.

6.3 Shelf life: 36 months from the date of manufacture.

6.4 Special precautions for storage: Store at temperature between 15°C - 30°C in a dark place. Do not freeze

6.5 Nature and contents of container:

10 ml plastic bottle.

6.6 Special precautions for disposal and other handling:

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS:

Marketing Authorization holder:

Registered office:

Centaur Pharmaceuticals Pvt. Ltd. Centaur House, Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai 400 055, India

Manufacturing Site:

Centaur Pharmaceuticals Pvt. Ltd. Plant I, Plot No: 3, 5B, 2C, Tivim Industrial Estate, Karaswada, Mapusa Goa-403526

8. MARKETING AUTHORISATION NUMBER

No. 158 (172)MFG/DFDA/97/852

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION
14.05.1999

10. DATE OF REVISION OF THE TEXT: AUGUST 2019

11. DOSIMETRY (IF APPLICABLE): NOT APPLICABLE.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

NOT APPLICABLE.